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S. 2080

To amend the Federal Food, Drug, and Cosmetic Act to require that food that contains a genetically engineered material, or that is produced with a genetically engineered material, be labeled accordingly, and for other purposes.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 22, 2000

Mrs. BOXER introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require that food that contains a genetically engineered material, or that is produced with a genetically engineered material, be labeled accordingly, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Genetically Engineered
5 Food Right-to-Know Act”.

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

1 (1) In 1999, 98,600,000 acres in the United
2 States were planted with genetically engineered
3 crops, and more than $\frac{1}{3}$ of the soybean crop, and
4 $\frac{1}{4}$ of the corn crop, in the United States was geneti-
5 cally engineered.

6 (2) The process of genetically engineering foods
7 results in the material change of such foods.

8 (3) The health and environmental effects of ge-
9 netically engineered foods are not yet known.

10 (4) Individuals in the United States have the
11 right to know whether food contains or has been
12 produced with genetically engineered material.

13 (5) Federal law gives individuals in the United
14 States the right to know whether food contains arti-
15 ficial colors and flavors, chemical preservatives, and
16 artificial sweeteners by requiring the labeling of such
17 food.

18 (6) Requirements that genetically engineered
19 food be labeled as genetically engineered would in-
20 crease consumer knowledge about, and consumer
21 control over consumption of, genetically engineered
22 food.

23 (7) Genetically engineered material can be de-
24 tected in food at levels as low as 0.1 percent by rea-
25 sonably available technology.

1 **SEC. 3. LABELING REGARDING GENETICALLY ENGINEERED**
 2 **MATERIAL; AMENDMENTS TO FEDERAL**
 3 **FOOD, DRUG, AND COSMETIC ACT.**

4 (a) IN GENERAL.—Section 403 of the Federal Food,
 5 Drug, and Cosmetic Act (21 U.S.C. 343) is amended by
 6 adding at the end the following paragraph:

7 “(t)(1) If it contains a genetically engineered mate-
 8 rial, or was produced with a genetically engineered mate-
 9 rial, unless it bears a label (or labeling, in the case of a
 10 raw agricultural commodity) that provides notices in ac-
 11 cordance with each of the following requirements:

12 “(A) The label or labeling bears the following
 13 notice: ‘GENETICALLY ENGINEERED’.

14 “(B) The label or labeling bears the following
 15 notice: ‘THIS PRODUCT CONTAINS A GENETI-
 16 CALLY ENGINEERED MATERIAL, OR WAS
 17 PRODUCED WITH A GENETICALLY ENGI-
 18 NEERED MATERIAL’.

19 “(C) The notice required in clause (A) imme-
 20 diately precedes the notice required in clause (B)
 21 and the type for the notice required in clause (A) is
 22 not less than twice the size of the type for the notice
 23 required in clause (B).

24 “(D) The notice required in clause (B) is the
 25 same size as would be required if the notice provided

1 nutrition information that is required in paragraph
2 (q)(1).

3 “(E) The notices required in clauses (A) and
4 (B) are clearly legible and conspicuous.

5 “(2) This paragraph does not apply to food that—

6 “(A) is served in restaurants or other similar
7 eating establishments, such as cafeterias and
8 carryouts;

9 “(B) is a medical food as defined in section
10 5(b) of the Orphan Drug Act; or

11 “(C) was grown on a tree that was planted be-
12 fore the date of enactment of the Genetically Engi-
13 neered Food Right-to-Know Act, in a case in which
14 the producer of the food does not know if the food
15 contains a genetically engineered material, or was
16 produced with a genetically engineered material.

17 “(3) In this paragraph:

18 “(A) The term ‘genetically engineered material’
19 means material derived from any part of a geneti-
20 cally engineered organism, without regard to wheth-
21 er the altered molecular or cellular characteristics of
22 the organism are detectable in the material.

23 “(B) The term ‘genetically engineered orga-
24 nism’ means—

1 “(i) an organism that has been altered at
2 the molecular or cellular level by means that are
3 not possible under natural conditions or proc-
4 esses (including recombinant DNA and RNA
5 techniques, cell fusion, microencapsulation,
6 macroencapsulation, gene deletion and doubling,
7 introduction of a foreign gene, and a process
8 that changes the positions of genes), other than
9 a means consisting exclusively of breeding, con-
10 jugation, fermentation, hybridization, in vitro
11 fertilization, or tissue culture; and

12 “(ii) an organism made through sexual or
13 asexual reproduction, or both, involving an or-
14 ganism described in subclause (i), if possessing
15 any of the altered molecular or cellular charac-
16 teristics of the organism so described.

17 “(C) The term ‘produced with a genetically en-
18 gineered material’, used with respect to a food,
19 means a food if—

20 “(i) the organism from which the food is
21 derived has been injected or otherwise treated
22 with a genetically engineered material (except
23 that the use of manure as a fertilizer for raw
24 agricultural commodities may not be construed

1 to be production with a genetically engineered
2 material);

3 “(ii) the animal from which the food is de-
4 rived has been fed genetically engineered mate-
5 rial; or

6 “(iii) the food contains an ingredient that
7 is a food to which subclause (i) or (ii) applies.”.

8 (b) GUARANTY.—

9 (1) IN GENERAL.—Section 303(d) of the Fed-
10 eral Food, Drug, and Cosmetic Act (21 U.S.C.
11 333(d)) is amended—

12 (A) by striking “(d)” and inserting
13 “(d)(1)”; and

14 (B) by adding at the end the following
15 paragraph:

16 “(2)(A) No person shall be subject to the penalties
17 of subsection (a)(1) or (h) for a violation of section 301(a),
18 301(b), or 301(c) involving food that is misbranded within
19 the meaning of section 403(t) if such person (referred to
20 in this paragraph as the ‘recipient’) establishes a guaranty
21 or undertaking that—

22 “(i) is signed by, and contains the name and
23 address of, a person residing in the United States
24 from whom the recipient received in good faith the

1 food (including the receipt of seeds to grow raw agri-
2 cultural commodities); and

3 “(ii) contains a statement to the effect that the
4 food does not contain a genetically engineered mate-
5 rial or was not produced with a genetically engi-
6 neered material.

7 “(B) In the case of a recipient who, with respect to
8 a food, establishes a guaranty or undertaking in accord-
9 ance with subparagraph (A), the exclusion under such sub-
10 paragraph from being subject to penalties applies to the
11 recipient without regard to the manner in which the recipi-
12 ent uses the food, including whether the recipient is—

13 “(i) processing the food;

14 “(ii) using the food as an ingredient in a food
15 product;

16 “(iii) repacking the food; or

17 “(iv) growing, raising, or otherwise producing
18 the food.

19 “(C) No person may avoid responsibility or liability
20 for a violation of section 301(a), 301(b), or 301(c) involv-
21 ing food that is misbranded within the meaning of section
22 403(t) by entering into a contract or other agreement that
23 specifies that another person shall bear such responsibility
24 or liability, except that a recipient may require a guaranty
25 or undertaking as described in this subsection.

1 “(D) In this paragraph, the terms ‘genetically engi-
 2 neered material’ and ‘produced with a genetically engi-
 3 neered material’ have the meanings given the terms in sec-
 4 tion 403(t).”.

5 (2) FALSE GUARANTY.—Section 301(h) of the
 6 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 7 331(h)) is amended by inserting “or 303(d)(2)” be-
 8 fore “, which guaranty or undertaking is false” the
 9 first place it appears.

10 (c) UNINTENDED CONTAMINATION.—Section 303(d)
 11 of the Federal Food, Drug, and Cosmetic Act, as amended
 12 by subsection (b)(1), is further amended by adding at the
 13 end the following paragraph:

14 “(3)(A) No person shall be subject to the penalties
 15 of subsection (a)(1) or (h) for a violation of section 301(a),
 16 301(b), or 301(c) involving food that is misbranded within
 17 the meaning of section 403(t) if—

18 “(i) such person is an agricultural producer and
 19 the violation occurs because food that is grown,
 20 raised, or otherwise produced by such producer,
 21 which food does not contain a genetically engineered
 22 material and was not produced with a genetically en-
 23 gineered material, is contaminated with a food that
 24 contains a genetically engineered material or was

1 produced with a genetically engineered material (in-
2 cluding contamination by mingling the 2 foods); and

3 “(ii) such contamination is not intended by the
4 agricultural producer.

5 “(B) Subparagraph (A) does not apply to an agricul-
6 tural producer to the extent that the contamination occurs
7 as a result of the negligence of the producer.”.

8 (d) CIVIL PENALTIES.—Section 303 of the Federal
9 Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amend-
10 ed by adding at the end the following subsection:

11 “(h)(1) With respect to a violation of section 301(a),
12 301(b), or 301(c) involving food that is misbranded within
13 the meaning of section 403(t), any person engaging in
14 such a violation shall be liable to the United States for
15 a civil penalty in an amount not to exceed \$1,000 for each
16 such violation.

17 “(2) Paragraphs (3) through (5) of subsection (g)
18 apply with respect to a civil penalty assessed under para-
19 graph (1) to the same extent and in the same manner as
20 such paragraphs (3) through (5) apply with respect to a
21 civil penalty assessed under paragraph (1) or (2) of sub-
22 section (g).”.

1 **SEC. 4. GRANTS FOR RESEARCH ON GENETICALLY ENGI-**
 2 **NEERED FOOD.**

3 Chapter IX of the Federal Food, Drug, and Cosmetic
 4 Act (21 U.S.C. 391 et seq.) is amended by adding at the
 5 end the following:

6 **“SEC. 908. GRANTS FOR RESEARCH ON GENETICALLY ENGI-**
 7 **NEERED FOOD.**

8 “(a) IN GENERAL.—The Secretary may make grants
 9 to appropriate individuals, organizations, and institutions
 10 to conduct research into the public health and environ-
 11 mental risks associated with genetically engineered mate-
 12 rials, food that contains a genetically engineered material,
 13 and food that is produced with a genetically engineered
 14 material, including risks related to—

15 “(1) increased allergenicity;

16 “(2) increased toxicity;

17 “(3) cross-pollination between genetically engi-
 18 neered materials and materials that are not geneti-
 19 cally engineered materials; and

20 “(4) interference with the soil ecosystem and
 21 other impacts on the ecosystem.

22 “(b) AUTHORIZATION OF APPROPRIATIONS.—

23 “(1) IN GENERAL.—There is authorized to be
 24 appropriated \$5,000,000 for fiscal year 2001 to
 25 carry out the objectives of this section.

1 “(2) AVAILABILITY.—Any sums appropriated
 2 under the authorization contained in this subsection
 3 shall remain available, without fiscal year limitation,
 4 until expended.

5 “(c) DEFINITIONS.—The terms ‘genetically engi-
 6 neered material’ and ‘produced with a genetically engi-
 7 neered material’ have the meanings given the terms in sec-
 8 tion 403(t)(3) of the Federal Food, Drug, and Cosmetic
 9 Act.”.

10 **SEC. 5. CONFORMING AMENDMENTS.**

11 (a) Section 1(n) of Public Law 90–201 is amended—

12 (1) in paragraph (11), by striking “or” at the
 13 end;

14 (2) in paragraph (12), by striking the period at
 15 the end and inserting “; or”; and

16 (3) by adding at the end the following:

17 “(13) if—

18 “(A) it contains a genetically engineered
 19 material, or was produced with a genetically en-
 20 gineered material; and

21 “(B)(i) it does not bear a label or labeling,
 22 as appropriate, that provides the notices re-
 23 quired under the terms and conditions of sec-
 24 tion 403(t) of the Federal Food, Drug, and
 25 Cosmetic Act (21 U.S.C. 343(t)); or

1 “(ii) it is the subject of a false guaranty or
2 undertaking,
3 subject to the terms and conditions of section 303(d)
4 of that Act (21 U.S.C. 333(d)) and subject to the
5 penalties described in section 303(h) of that Act (21
6 U.S.C. 333(h)) and remedies available under this
7 Act.”.

8 (b) Section 4(h) of Public Law 85–172 is amended—

9 (1) in paragraph (11), by striking “or” at the
10 end;

11 (2) in paragraph (12), by striking the period at
12 the end and inserting “; or”; and

13 (3) by adding at the end the following:

14 “(13) if—

15 “(A) it contains a genetically engineered
16 material, or was produced with a genetically en-
17 gineered material; and

18 “(B)(i) it does not bear a label or labeling,
19 as appropriate, that provides the notices re-
20 quired under the terms and conditions of sec-
21 tion 403(t) of the Federal Food, Drug, and
22 Cosmetic Act (21 U.S.C. 343(t)); or

23 “(ii) it is the subject of a false guaranty or
24 undertaking,

1 subject to the terms and conditions of section 303(d)
2 of that Act (21 U.S.C. 333(d)) and subject to the
3 penalties described in section 303(h) of that Act (21
4 U.S.C. 333(h)) and remedies available under this
5 Act.”.

6 **SEC. 6. EFFECTIVE DATE.**

7 This Act and the amendments made by this Act take
8 effect 180 days after the date of enactment of this Act.

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